[0012] There are many inventions described and illustrated herein. The described inventions are neither limited to any single aspect nor embodiment thereof, nor to any combinations and/or permutations of such aspects and/or embodiments. Moreover, each of the aspects of the described inventions, and/or embodiments thereof, may be employed alone or in combination with one or more of the other aspects of the described inventions and/or embodiments thereof. For the sake of brevity, certain permutations and combinations are not discussed and/or illustrated separately herein. Notably, an embodiment or implementation described herein as "exemplary" is not to be construed as preferred or advantageous, for example, over other embodiments or implementations; rather, it is intended reflect or indicate the embodiment(s) is/are "example" embodiment (s).

[0013] FIGS. **1**A and **1**B are graphs showing viscosities of exemplary antibody solutions as a function of antibody concentration, formulation, and temperature.

[0014] FIGS. **2**A and **2**B are schematic drawings of components of an exemplary primary packaging component suitable for overfilling, according to the present disclosure.

[0015] FIG. **3**A is a schematic drawing of an exemplary overfilled and stoppered primary packaging component, according to the present disclosure.

[0016] FIG. **3**B is another schematic drawing of an exemplary overfilled and stoppered primary packaging component, according to the present disclosure.

[0017] FIGS. **3**C and **3**D are partial schematic drawings of stoppered primary packaging components, according to the present disclosure.

[0018] FIG. **4** is a flow diagram of an exemplary method for overfilling a primary packaging component, according to the present disclosure.

[0019] FIGS. **5**A-**5**D are schematic drawings of steps in an exemplary process of stoppering an overfilled primary packaging component.

[0020] FIGS. **6**A-**6**E are schematic drawings of steps in another exemplary process of stoppering an overfilled primary packaging component.

[0021] As used herein, the terms "comprises," "comprising," "includes," "including," or any other variation thereof, are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements, but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. The term "exemplary" is used in the sense of "example," rather than "ideal." In addition, the terms "first," "second," and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish an element, a structure, a step or a process from another. Moreover, the terms "a" and "an" herein do not denote a limitation of quantity, but rather denote the presence of one or more of the referenced items.

DETAILED DESCRIPTION

[0022] Embodiments of the present disclosure relate to systems and methods for overfilling primary packaging components. For example, embodiments of the present disclosure may relate to systems and methods for overfilling drug containers, such as syringes. More particularly, embodiments of the present disclosure may relate to, e.g., systems and methods for overfilling prefillable syringes ("PFS") for packaging, sale, and commercial use. "Overfilling" in the context of the present disclosure refers to filling of a container with a larger volume of a substance than the nominal volume of the container, while still maintaining a desired level of safety and/or integrity as to the container and its contents.

[0023] The "nominal volume" (also called the "specified volume," or "specified capacity") of a container refers to the container's maximum capacity, as identified by the container's manufacturer or a safety standards organization. A manufacturer or a safety standards organization may specify a container's nominal volume to indicate that the container can be filled with that volume of fluid (either aseptically or not) and be closed, stoppered, sterilized, packaged, transported, and/or used while maintaining container closure integrity, and while maintaining the safety, sterility, and/or aseptic nature of the fluid contained inside. In determining the nominal volume of a container, a manufacturer or a safety standards organization may also take into account variability that occurs during normal filling, closing, stoppering, packaging, transportation, and administration procedures. As an example, a prefillable syringe may be either hand- or machine-filled with up to its nominal volume of fluid, and may then be either vent tube- or vacuum-stoppered, without the filling and stoppering machinery and tools touching and potentially contaminating the contents of the syringe.

[0024] Overfilling a container may include filling the container with more than its nominal volume of fluid. For example, overfilling a PFS having a nominal volume of 1 mL of fluid may include filling a barrel of the PFS with more than 1 mL of fluid and stoppering the PFS such that the stopper is unlikely to be moved, dislodged, or otherwise compromised during routine packaging, transport, or administration, as will be discussed in greater detail below.

[0025] The term "formulated drug substance" refers to a substance including a therapeutic ingredient (e.g., an active pharmaceutical ingredient such as a biologic or a traditional pharmaceutical chemical) and one or more excipients and diluents. The term "drug product," as used herein, may refer to a volume of a formulated drug substance apportioned into a primary packaging component for packaging, transportation, delivery, and/or administration to a patient.

[0026] The term "primary packaging component" refers to a packaging component for a drug, such as a drug container, that is designed and manufactured to be in direct physical contact with the formulated drug substance. (See, for example, Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research (May 1999), which is incorporated by reference herein.) Examples of primary packaging components include prefillable syringes, Luer syringes, cartridges, and vials made of glass, plastic, and/or other materials.

[0027] It is generally desired that a primary packaging component in which a formulated drug substance is packaged (e.g., in an aseptic filling process or a non-aseptic filling process), sterilized, sold, and/or used be able to contain a suitable or desired amount of the formulated drug substance for use (such as, for example, a single dose of the formulated drug substance), while also being able to withstand packaging processes, transportation, and use while remaining secure and closed, maintaining structural integrity